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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,722	10/19/2001	Seishi Kato	2001_1023A	8828

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EXAMINER	
KATCHEVES, KONSTANTINA T	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/889,722	KATO ET AL.	
	Examiner	Art Unit	
	Konstantina Katcheves	1636	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *23 December 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *2,3,5,6,8 and 9*.

Claim(s) withdrawn from consideration: *1,4 and 7*.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

JAMES KETTER
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because: Applicant has provided no new unrebutted arguments. Specifically, Applicant argues in the remarks filed 23 December 2004:

"In the instant case, the disclosed use is substantial and credible. The specification discloses that the claimed polynucleotide encodes a novel human nuclear protein consisting of 704 amino acids, which contains a WW domain, and which exists in cellular nuclei. The specification further discloses that human nuclear proteins have well established functions, such as transcription factors, splicing factors, intranuclear receptors, cell cycle regulators, ttlmor suppressors, etc. Specification, page 1, lines 24-30. The specification also discloses that the protein of the instant invention shares high homology with known human nuclear proteins. The specification also establishes that the human nuclear protein encoded by the claimed polynucleotide contains a WW domain, and that it is well established that WW domains are contained in the cytoskeleton system. The specification indicates that the claimed protein is involved in the signal transduction, as well as in ubiquitin-protein ligase in the protein degradation system and in a transcription activator. Specification, page 2, lines 5-20, page 10, lines 20-23. The Applicants also found that the protein encoded by the claimed polynucleotide binds the c-terminal domain of RNA polymerase and is involved in mRNA synthesis."

These very arguments are found on page 7 of Applicant's remarks filed 23 March 2004 and rebutted in the Examiners final rejection mailed on 23 June 2004.

MPEP 2107 establishes the Utility examination guidelines the examiner must use to establish a prima facie showing of lack of utility. "Any rejection based on lack of utility should include a detailed explanation why the claimed invention has no specific and substantial credible utility. Whenever possible, the examiner should provide documentary evidence regardless of publication date (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents) to support the factual basis for the prima facie showing of no specifi and substantial credible utility. If documentary evidence is not available, the examiner should specifically explain the scientific basis for his or her factual conclusions.. ..The prima facie showing must contain the following elements: (i) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established; (ii) Support for factual findings relied upon in reaching this conclusion; and (iii) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art. The examiner has met this burden and supported this position in view of Applicant's rebuttal as well.

As previously stated by the examiner, without specific knowledge as to the function of the polmucleotide of SEQ ID NO:1 or the protein it encodes, each of these utilities is a general assertion and not a specifically asserted utility. Applicant makes a general statement of diagnostic and treatment utilities for the claimed sequence.

According to MPEP 2101.01:

"[I]ndicating that a compound may be useful in treating unspecified disorders, or that the compound has "useful biological" properties, would not be sufficient to define a specific utility for the compound. Similarly, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. A general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed. Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition. Assertions falling within the latter category are sufficient to identify a specific utility for the invention. Assertions that fall in the former category are insufficient to define a specific utility for the invention, especially if the assertion takes the form of a general statement that makes it clear that a "useful" invention may arise from what has been disclosed by the applicant. Knapp v. Anderson, 477 F.2d 588, 177 USPQ 688 (CCPA 1973).

The biological activity of that sequence is not established moreover specific DNA targets are not disclosed or known such that Applicants assertion that the sequence may treat or diagnose unspecified disease lacks specific and substantial utility in accordance with the guidance found in the MPEP. Therefore, a specific utility for the claimed polynucleotide has not been asserted. Applicant argues that a biological activity of the polmucleotide is established based on homology data which discloses a WW domain in the sequence and that th specification teaches that human nuclear receptors have various well-established functions. In Applicant's specification, table 1 discloses a comparison of various sequence with homology to the WW domain of the present invention. Applicant is reminded that homology does not necessadly correlate to function. which is recognized in the art cited by the examiner. Second, WW domains are found in protein with varied functions such that the mere presence of a WW domain does not correlate to biological activity, as Applicant asserts. The WW domain is related to proteins with many activities such as transcription factors, splicing factors, intranuclear receptors, cell cycle regulators, tumor suppressors etc." See Applicant's remarks, page 7 and Specitkation, page 1. Moreover, in considering the compared sequences in table 1, Accession number P476937, also has a WW domain, is disclosed by Chen et al. J. Biol. Chem. Vol. 272 no. 27 pp17070-7 1997. Chen et al. also recognize the diversity of proteins having WW domains: "the WW domain is shared by proteins of diverse functions including structural, regulatory, and signaling proteins in yeast, nematode and mammals." Given this understanding in the art and the teaching of the MPEP